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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,753	11/01/2000	Robert E. Dudley	9774100-0024	2099

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Joseph A. Mahoney
Mayer, Brown & Platt
P.O. Box 2828
Chicago, IL 60690

[REDACTED] EXAMINER

JIANG, SHAOJIA A

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1617

DATE MAILED: 11/23/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Candidate(s)	
	09/703,753	DUDLEY, ROBERT E	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 August 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33, 35-49, and 51-100 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 51-56 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 32-33, 35-43, 45-49, 57-73, and 75-100 is/are rejected.
- 7) Claim(s) 44 and 74 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicant's affirmation of the telephonic election of the invention of Group III, Claims 32-50 in Paper No. 8, submitted August 24, 2001 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

This Office Action is a response to Applicant's amendment and response filed on August 24, 2001 in Paper No. 8 wherein claims 32, 35-36, 38-39, 41-46, and 48-49 have been amended, and claims 34 and 50 have been cancelled, and claims 57-100 are newly submitted. Currently, claims 1-33, 35-49, and 51-100 are pending in this application.

This application contains claims 1-31 and 51-56 drawn to inventions nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment (amended claim 49) and remarks with respect to the objection to claim 49 for minor informalities of record in the Office Action dated April 24,

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2001 have been fully considered and are found persuasive. Therefore, this said objection is withdrawn.

Applicant's amendment with respect to the objection to claim 50 made under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim (rejection of record in the Office Action dated April 24, 2001) has been fully considered and are found persuasive to remove the objection since claim 50 has been cancelled.

Applicant's amendment with respect to the rejection of claims 35-36, 38-39, 41-46, 48, and 50 made under 35 U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention of record stated in the Office Action dated April 24, 2001 have been fully considered and are found persuasive as to remove the rejection of claims 35-36, 38-39, 41-46, 48, and 50 since claims 35-36, 38-39, 41-46, and 48-49 have been amended and claim 50 has been cancelled. Therefore, the said rejection is withdrawn.

Claim Objection

The following is a new objection necessitated by Applicant's amendment:

Claims 84-87, 94, and 100 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well

settled that recitation of an inherent property of a composition or method will not further limit claims drawn to a composition or method. In the instant case, for example, "stimulating hormone serum level concentration in the subject" in claim 84 is an inherent property of the composition herein. Further, "wherein the subject achieves hormonal steady state levels of testosterone" in the bottom line of claim 100 is not further limit the claim but is a substantial duplicate of claim 32.

Claim Rejections - 35 USC § 112

The following is a new rejection necessitated by Applicant's amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 41-43, and are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The employment of a comma between sildenafil and citrate in claim 35 renders claim 35 indefinite as to whether citrate is intended to be a pharmaceutical encompassed thereby.

Claim 41 recites the limitation "the composition" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites the limitation "the enhancer" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 43 recites the limitation "the thickener" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-33, 35-43, 45-49, 57-73, and 75-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omar (5,730,987, A, PTO-892) and Mak et al. (N, PTO-892) and Moreland et al. (U, PTO-892) in view of Allen (O, PTO-892) essentially for reasons of record stated in the Office Action dated April 24, 2001. The combined teachings Omar, Mak et al. and Moreland et al. in view of Allen clearly render the claimed invention as amended on August 24, 2001 obvious as also discussed further below.

Applicant's remarks filed on August 24, 2001 in Paper No. 8 with respect to the rejection of claims 32-50 made under 35 U.S.C. 103(a) as being unpatentable over Omar and Mak et al. and Moreland et al. in view of Allen for reasons of record stated in the Office Action dated April 24, 2001 have been fully considered but are not deemed persuasive as to the patentability of claims 32-43 and 45-49 or newly added claims 57-74 and 75-100 over the prior art for the following reasons.

Applicant's assertion that "there is no motivation to combine the cited references" and "the Office Action does not cite any reference showing or suggesting the interchangeability of these elements" are not found persuasive. It has been held that it is *prima facie* obvious to combine two agents each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. In the instant case, as discussed in the previous Office Action, the particular steroid, testosterone, and yohimbine HCl (ACTIBINE) or a combination thereof to be administered are known to be useful in the composition and the method of the treatment of impotence in human males, i.e., erectile dysfunction, based on the teaching of Omar. Moreover, the phosphodiesterase type 5 inhibitor, sildenafil, is well known to be useful in the treatment of male erectile dysfunction according to Moreland et al. Thus, the motivation to combine testosterone and the phosphodiesterase type 5 inhibitor, sildenafil, or yohimbine HCl broadly to form a single composition useful for the very same purpose is clearly seen since the combination of testosterone and yohimbine HCl or yohimbine HCl alone or sildenafil are all known to be useful in the treatment of male erectile dysfunction based on the cited prior art. At least additive therapeutic effects would have been reasonably expected.

Further, the motivation to employ known drug delivery systems to enhance the penetration of actives herein transdermally (percutaneously) or topically for treating male erectile dysfunction is clearly provided by the Mak et al. and Allen references. As

discussed in the previous Office Action, Mak et al. discloses an enhancement of the penetration of transdermally (percutaneously) or topically applied pharmaceutical compositions comprising the active steroid agent, testosterone, and a penetration-enhancing system that comprises oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and the gelling agent (thickener), CARBOPOL (a polyacrylic acid). Allen also discloses a topical cream composition useful for treating male erectile dysfunction comprising the particular penetration enhancer herein, isopropyl myristate. Therefore, the combined teachings of Mak et al. and Allen clearly suggest the interchangeability of these elements in the composition of the instant method versus the prior art for the purpose of improving the penetration of steroid actives herein from transdermally or topically applicable compositions useful to treat male erectile dysfunction. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145. Further, the use of the composition excipients and carriers materials herein is clearly motivated by the prior art as they are known to be useful in similar compositions.

Since all active composition components herein are known to useful to treat male erectile dysfunction, it is considered *prima facie* obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected based on the well settled principle set forth *In re Kerkhoven* regarding combination inventions. Therefore,

motivation to combine the teachings of the prior art to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

The results in the tests of the employment of known drug delivery systems for the penetration of actives herein transdermally or topically for treating male erectile dysfunction shown in Examples 1-6 in the specification (page 15-55) have been fully considered but are not deemed persuasive as to unexpected results for the claimed invention over the prior art for reasons below. The results in Example 1-6 are seen to merely demonstrate an expected effect based on the prior art since all active composition components herein are known to be useful to treat male erectile dysfunction. See MPEP § 716.02(c). Moreover, the tests herein merely employ two known particular drug delivery systems, AndroGel® and ANDRODERM®, encompassed by the claimed method. Thus, the evidence in the testing is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of actives and drug delivery systems herein. See MPEP § 716.02(d). The evidence in Examples 1-6 provides no side-by-side comparison with the closest prior art in support of nonobviousness or unexpected results for the instant claimed invention over the same.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection of claims 32-33, 35-43, 45-49, 57-73, 75-100 is adhered to.

Claim Objection

Claims 44 and 74 are objected to as being dependent upon a rejected base claim 32, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claimed method of treating male erectile dysfunction employing the specified combination of agents in claims 44 and 74 in the recited amounts is not seen to be taught or fairly suggested by the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
November 14, 2001

Minna Moezie
MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600